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5/10/99

Document Control Office (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency
Washington, DC 20460-0001

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Dear Sir:

The information provided in this letter is submitted to the U.S. Environmental Protection Agency (EPA) by [redacted] under Section 8(e) of the Toxic Substances Control Act (TSCA).

On May 4, 1999, I became aware of the results of a dose range-finding (pilot) and 28-day repeat dose oral study of 1-chloromethyl-4-fluoro-1,4-diazoniabicyclo [2.2.2]octane bis(tetrafluoroborate) (CASRN 140681-55-6) in the rat. Some of the clinical signs observed in the pilot study appear to meet the TSCA 8(e) reporting requirement. The signs in question were not observed in the 28-day oral study. This substance, which is used in the manufacture of pharmaceutical intermediates, has also been found to be of low toxicity in a standard dermal LD_{50} test.

The appropriate personnel at [redacted] have been notified about these findings and instructed in appropriate safety precautions. The relevant MSDS has been modified accordingly.

Complete and "sanitized" copies of the summary of the test results and a "sanitized" copy of this letter are attached. If you need additional information, please feel free to contact me at [redacted] or [redacted] at [redacted].

Sincerely,

[redacted]

Attachment

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Test material information

Sample ID: 1-Chloromethyl-4-fluoro-1,4-diazoniabicyclo[2.2.2]octane bis(tetrafluoroborate)

CAS #: 140681-55-6

Sample description: White powder with a purity of 98.3%

Study descriptions and results

- A 6 to 7-day pilot oral toxicity study was conducted in rats at [redacted] to set doses for a 28-day repeated dose study. Dose levels of 75, 150, 300, 500, 750, and 1000 mg/kg were tested.

  Piloerection, unawareness of surroundings, lethargy, loss of body tone, limited use of limbs, waddling, unsteady gait (walking in circles), splaying of hind limbs, rigid tail and walking on toes was observed at 1000 and 750 mg/kg. The animals in these dose groups were sacrificed on Day 2. Necropsy of the animals that received ≥750 mg/kg/day revealed abnormalities of the kidneys and gastrointestinal tract. One animal dosed at 500 mg/kg exhibited lethargy, loss of body tone, piloerection, partially closed eyes and unawareness of